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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,811	11/25/2003	Charles Hensley	33205.0217	8179

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,811	HENSLEY ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13-20,22 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13-20,22 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 11, 13-20, 22 and 41 are pending in this application.

Applicant's election of the invention of Group I, the subject matter of which Group I is explicitly set forth in the Office action of 10/26/2004, in the reply filed on 1/3/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 11, 13-20, 22 and 41 will presently be examined to the extent that they read on the elected subject matter of record, i.e. composition and method wherein the active substance is zinc and there is no additional viscosity claim requirement.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 13-19, 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly (US 5,208,031).

Kelly explicitly discloses zinc compositions that contain a fluid and thickening agent. Claim 1 discloses a sexual lubricant mixture within a watertight deformable container which allows the mixture to be warmed before use. The mixture contains (a) water, (b) thickening agent such as cellulose and chemically treated derivatives, various

gums, (c) lubricating agent such as glycerin, and (d) zinc salt, which releases zinc ions when dissolved in aqueous carrier substance (claim 1). No irritation of the mucous membranes of an uninfected person is disclosed (claim 1). Zinc gluconate is specifically claimed (claim 2). 0.5-3% zinc salt concentration is taught (sentence bridging columns 16 and 17). This means carriers for zinc salt comprise 97-99.5% of the composition. With respect to thickening agent (b), Kelly teaches hydroxyethylcellulose as a chemically-treated cellulose derivative (column 8, line 9).

The claim language, "composition for delivering an active substance to a nasal membrane" is noted, but keeping in mind that the rejected claims are all directed to the composition per se, there is nothing about Kelly's composition that would prevent it from functioning as claimed by applicant. Kelly's composition can be warmed and applied to the genital mucous membranes, so it would also inherently have the functionality of delivering zinc gluconate to the nasal membrane. The watertight deformable container meets the system and applicator language of claim 41. This is sufficient for anticipation of a composition claim. MPEP 2112, 2112.01.

Purified water of applicant's claim 14 would necessarily have been present in Kelly's lubricant mixture, which must utilize such water due to its application in the genital mucosae and resultant lack of irritation. Additionally, distilled water is disclosed by Kelly (column 20, line 47). The language, "further comprising a salt" in applicant's

claim 19 is interpreted to encompass zinc gluconate because zinc is the only substance that is required in independent claim 11.

The claims are thereby anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 13, 14, 17-20, 22 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/05330 in view of Eby, III (Re. 33,465, hereinafter referred to as "Eby") and Martindale The Extra Pharmacopoeia (hereinafter, "Martindale").

WO 94/05330 teaches nasal pharmaceutical products in sprayable form whereby upon contact with the mucous linings of the nasal cavity, the viscosity of the composition increases to form a gel, which minimizes the "roll-back" problem associated with drops and non-gellable nasal formulations (page 1, first paragraph). The formulation has a pH range of about 2.5 to 6 and contains 0.05 to 5 wt% carboxyl-containing polymer, 0 to 1 wt% surfactant, and 0.005 to 5 wt% nasal medicament (paragraph bridging pages 3 and 4). A preferred surfactant is sodium lauryl sulfate,

which is a salt (page 7, lines 14-15). The nasal medicament is defined as "a drug suitable for application via the nasal cavity" (page 10, lines 21-22) and includes chemotherapeutic agents that treat a nasal or upper respiratory disease (page 10, lines 28-29; page 11, line 5).

Eby teaches reduction in the duration of common cold symptoms such as nasal drainage, nasal obstruction, sore throat, fever, cough, which are the result of upper respiratory infection (column 2, lines 57-64) by applying to the nasal mucosal membrane a zinc compound (column 2, lines 64-68). Nasal sprays, nasal drops, nasal ointments, nasal washes and nasal injections are taught (column 3, lines 3-7). Zinc gluconate is taught (column 3, line 24).

Martindale is cited to establish that glycerin (glycerol) is a common pharmaceutical excipient, which is known for its lubricating and moisturizing properties (pages 1374-75).

Although WO 94/05330 does not expressly disclose the use of zinc, or more specifically zinc gluconate, in its nasal pharmaceutical product and system, the reference clearly teaches the incorporation of suitable nasal medicament for treating a nasal or upper respiratory disease. Eby provides the motivation to utilize zinc gluconate as the nasal medicament in WO 94/05530 because Eby teaches zinc gluconate to be useful in reducing the duration of numerous common cold symptoms such as nasal drainage, nasal obstruction, sore throat, fever, cough, which are the result of upper

respiratory infection. At least 75 wt% water, e.g. purified water, is suggested by WO 94/05530 because purified water would be advantageous for application to the nasal mucosa, and purified water would be suitable as the major nasal composition excipient for the specified 0.05 to 5 wt% carboxyl-containing polymer, 0 to 1 wt% surfactant, and 0.005 to 5 wt% nasal medicament. Addition of glycerin in the nasal pharmaceutical product and system because glycerin would have been expected to provide additional moisturizing and/or lubricating properties, which would have been advantageous for product intended for intranasal use.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 13, 14, 15, 17-20, 22 and 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,673,835 in view of Martindale. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Patented claims 1-6 are directed to methods of delivering zinc into the blood by providing a mixture of zinc, 1.5 wt% zinc gluconate for example, and 75-99.999 wt% at least one carrier to the nasal membrane. Up to 5 wt% carbohydrate thickener is included in the mixture (claims 4-5).

Martindale is cited to establish that glycerin (glycerol) is a common pharmaceutical excipient, which is known for its lubricating and moisturizing properties (pages 1374-75).

Although a carrier fluid such as purified water is not expressly set forth in the patented claims, such carrier selection would have been obvious for a composition

intended for intranasal application. Incorporation of glycerin for further lubrication and moisturization would have been suggested due to the nature of intranasal application. Zinc gluconate is interpreted as meeting the feature of claim 19, because the gluconate ion makes it a salt, which delivers the zinc. Further, even though the invention of the patented claims are methods, the composition and a system comprising an applicator with the composition would have been obvious because the applicator and the composition must be utilized to practice the method.

For these reasons, one of ordinary skill in the art would have recognized the claimed invention as an obvious variation of the invention claimed in claims 1-6 of U.S. Patent No. 6,673,835 in view of Martindale.

U.S. Patent No. 6,929,800 (which is not prior art) is noted for the record. Claim 1 is reproduced hereinbelow:

> 1. A non-steroidal nasal passage cleaning composition comprising per 1000 ml. of water, 7.1 grams sodium chloride, 0.5 ml. methyl cylate 0.8 ml tea tree oil, 0.023 grams gum benzoin or balsam tolu, 0.025 grams camphor, or, 0.03 grams camphor, 0.03 grams menthol or peppermint oil, 20 ml. glycerin, 1.6 grams potassium alum, 1 gram zinc sulfate, 0.1 grams n-acetyl 1. cystine and 1 gram of alcohol.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Sreeni Padmanabhan, can be reached on **(571)272-0629**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600